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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,320 | 11/21/2003 | Kenneth James Kozak | 100736/0504851 | 3081 |

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EXAMINER

PORTNER, VIRGINIA ALLEN

| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,320

Applicant(s)

KOZAK, KENNETH JAMES

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending.

Claim Objections

1. Claims ^{are} 1, 7 ~~is~~ objected to because of the following informalities:
2. Claim 1 is number 1 and a mixture of letters (a) and numbers (1-4) are used in the subparagraphs following the preamble. It is confusing to see the combination of letters and numbers as it is not clear how each type designator is intended to correspond to the other.
3. Claims 4 and 7 recite the same claim limitations and both depend from claim 1; claim 7 is duplicative of claim 4 and is not further limiting of the claimed invention.
4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)) as evidenced by US Pat. 6,793,958.

6. Claims 1-16 are rejected under 35 U.S.C. 102(e), ^{Filing date = April 27, 2001} effective filing date October 29, 1998) as being anticipated by Reiter et al (US 2004/ 0023316 A1).

Reiter et al disclose the instantly claimed invention directed to a method of detecting *Helicobacter pylori* antigen (see pages 1 and 3, respectively, [0003], and [0020]) in a human fecal specimen (see title "stool", and page 4, [0038] "especially of human patients") the method comprising the steps of:

1) dispersing human fecal specimen in a protein based diluent ("skim milk" see page 13, paragraph [154] which contains casein (see US Pat. 6,793,958, Brief Summary paragraph 19, "instead of casein protein, it is possible to use skimmed milk protein"; Detailed Description test paragraph 4 "casein utilized in the present invention is preferably added as skimmed milk powder");

2) contacting the fecal specimen in the diluent with an antibody to form a complex (see page 13, [0154 "ELISA plates were coated for 1 hour at 37°C in 100 µl of an mAK solution (2.5 µg antibody/ml carbonate buffer, 0.1M, pH 9.5)"; a plurality of monoclonal antibodies were used, see Table 4, page 13; page 14, [0159 "combination" of monoclonal antibodies]);

3) exposing the complex to a second antibody that is labeled (see page 13, paragraph [0154, column 2, and Table 4]);

4) detecting (streptavidin with POD, produces a blue colored product) the amount of the labeled antibody (biotin labeled) in the complex and in turn determining the presence of *H. pylori* antigen in the fecal specimen (see page 13, Table 4).

Both the first and second monoclonal antibodies specific were genus specific antibodies, the epitopes to which they bound shown in Table 2, page 12, paragraph [0144]. The urease B subunit epitope (VGEVITR, amino acid sequence for epitope) is present in *Helicobacter pylori*, *H. heilmannii*, *H. felis*, *H. hepaticus*, *H. bizzozeronii*, *Helicobacter* sp. TD1 and *Campylobacter pylori* (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific). Additionally, a second monoclonal that is a genus specific monoclonal with binding specificity for the alpha subunit of *Helicobacter pylori* (LPLGRNA, amino acid sequence of epitope), would also immunoreact with this epitope that is present in *H. hepaticus* and *Campylobacter jejuni* (see Swiss-Prot Blast search alignments provided as evidence of the epitope binding specificity for the monoclonal antibodies to be genus specific).

Washes were carried out between steps (see page 11, [0142].
(Instant claims 13 and 16) Kits (see [0098] and claims 51-53) that comprise a plurality of monoclonal antibodies, diluents, solid support (see page 8, [0092-0093; 0075] devices, the solid support being defined to include microtiter plates, particles, gold colloidal particles, latex, test strips, to name a few.

The reference inherently anticipates the instantly claimed invention.

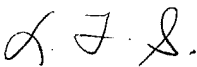
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 14, 2004


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600